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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Simon F. Williams, David P. Martin, and Frank A. Skraly

Serial No.: 10/082,954 Art Unit: Not Yet Assigned

Filed: February 26, 2002 Examiner: Not Yet Assigned

For: MEDICAL DEVICES AND APPLICATIONS OF POLYHYDROXYALKANOATE POLYMERS

Assistant Commissioner for Patents  
Washington, D.C. 20231

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit a Supplemental Information Disclosure Statement, including two (2) pages of Form PTO-1449 and copies of the documents cited therein.

This Supplemental Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account No. 50-1868.

**Foreign Documents**

| <u>Number</u> | <u>Publication Date</u> | <u>Patentee</u>            | <u>Country</u> |
|---------------|-------------------------|----------------------------|----------------|
| EPA 0 452 111 | 10-16-1991              | Takeda Chemical Industries | EP             |

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TC 1700

U.S.S.N.: 10/082,954  
Filed: February 26, 2002  
SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

### Publications

FRASER, et al., "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque," *Acta Endocrinol* 121:841-848 (1989).

HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic," *Phys Technol* 16:32-36 (1985).

KORSATKO, et al., "The influence of the molecular weight of poly-D(-)-3-hydroxybutyric acid on its use as a retard matrix for sustained drug release," *8<sup>th</sup> Europ. Congress of Biopharmaceutics and Pharmokinetics* 1:234-242 (1987).

MODELLI, et al., "Kinetics of aerobic polymer degradation in soil by means of the ASTM D 5988-96 standard method," *J Environ Polym Degr* 7:109-116 (1999).

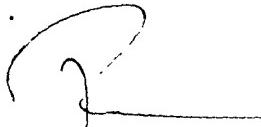
RENSTAD, et al., "The influence of processing induced differences in molecular structure on the biological and non-biological degradation of poly (3-hydroxybutyrate-co-3-hydroxyvalerate), P(3-HB-co-3-HV)," *Polymer Degradation and Stability* 63:201-211 (1999).

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**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Patrea L. Pabst  
Reg. No. 31,284

Dated: May 14, 2002

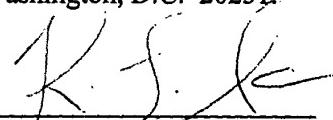
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Filed: February 26, 2002  
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**Certificate of Mailing under 37 CFR §1.8(a)**

I hereby certify that this Supplemental Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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Kimberly L. Adams

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|  |   | Complete if Known      |                   |
|  |   | Application Number     | 10/082,954        |
|  |   | Filing Date            | February 26, 2002 |
|  |   | First Named Inventor   | Simon F. Williams |
|  |   | Group Art Unit         |                   |
|  |   | Examiner Name          |                   |
|  |   | Attorney Docket Number | MBX 035 DIV       |
| Sheet  | 1 | of                     | 2                 |

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

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<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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|  |   | Examiner Name          |                   |
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|  |   | Attorney Docket Number | MBX 035 DIV       |

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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## **Sheef**

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of

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**Application Number**

10/082,954

**Filing Date**

February 26, 2002

**First Named Inventor**

**Simon E. Williams**

**Group Art Unit**

**Examiner Name**

## OTHER ART - NON PATENT LITERATURE DOCUMENTS

| Examiner's Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published                                     | T <sup>2</sup>                     |
|----------------------|-----------------------|--|------------------------------------|
|                      |                       | FRASER, et al., "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque," <i>Acta Endocrinol</i> 121:841-848 (1989).   |                                    |
|                      |                       | HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic," <i>Phys Technol</i> 16:32-36 (1985).   |                                    |
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